

PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449-PTO		<b>Complete if Known</b>	
		Application Number	10/612,650
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Filing Date	July 2, 2003
		First Named Inventor	S. Megati
		Group Art Unit	4645 1625
		Examiner Name	Not Yet Assigned - ZINNA DAVIS
		Attorney Docket Number	WYTH0015-100/AM100961
Sheet	1	of	3

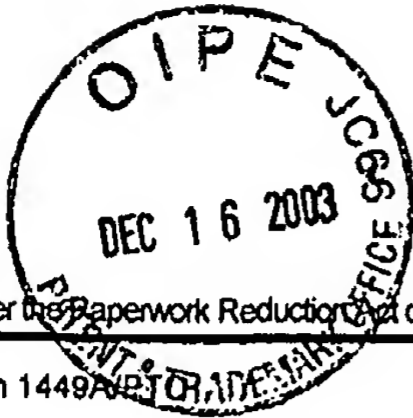
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
md	AA	Mendelsohn and Karas, "The protective effects of estrogen on the cardiovascular system," New Engl. J. Med. (1999) 340:1801-1811.	
	AB	Epperson, et al., "Gonadal steroids treatment of mood disorders," Psychosomatic Med. (1999) 61:676-697.	
	AC	Crandall, J. "Estrogen replacement therapy and colon cancer: a clinical review," Women's Health Gender-Based Med. (1999) 8:1155-1166.	
	AD	Monk and Brodaty, "Use of estrogens for the prevention and treatment of Alzheimer's disease," Dementia & Geriatric Cognitive Disorders (2000) 11:1-10	
	AE	Hurn and Macrae, "Estrogen as a neuroprotectant in stroke," J. Cerebral Blood Flow & Metab. (2000) 20:631-652.	
	AF	Calvin, "Oestrogens and wound healing," Maturitas (2000) 34:195-200.	
	AG	Finking, et al., "The effects of estrogen in the cardiovascular system," Zeitschrift fur Kardiologie (2000) 89:442-453.	
	AH	Brincat, "Hormone replacement therapy and the skin," Maturitas (2000) 35:107-117.	
	AI	Al-Azzawi, "The menopause and its treatment in perspective," Postgrad. Med. J. (2001) 77:292-304.	
	AJ	Moggs and Orphanides, "Estrogen receptors: orchestrators of pleiotropic cellular response," EMBO Reports (2001) 2:775-7781.	
md	AK	Hall, et al., "The multifaceted mechanisms of estradiol and estrogen receptor signaling," J. Biol. Chem. (2001) 276:36869-36872.	

Examiner Signature	Zinna Davis	Date Considered	11/5/2004
--------------------	-------------	-----------------	-----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

**Complete if Known**

Application Number	10/612,650
Filing Date	July 2, 2003
First Named Inventor	S. Megati
Group Art Unit	1645-1625
Examiner Name	Not Yet Assigned ZINNA DAVIS
Attorney Docket Number	WYTH0015-100/AM100961

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

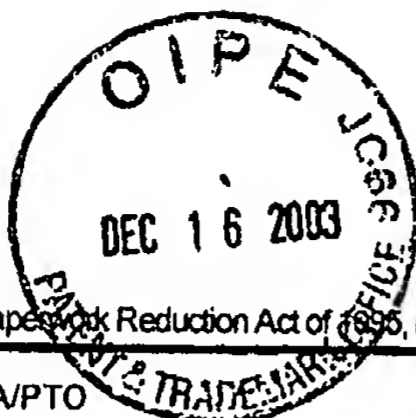
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
gnd	AL	McDonnell, "The mechanism of action of steroid hormone receptors," in Principles of Molecular Regulation, (2000) pp. 351-361	
	AM	McKenna, et al., "Nuclear receptor coregulators: cellular and molecular biology," Endocrine Rev. (1999) 20:321-344	
	AN	Quaedackers, et al., "4-Hydroxytamoxifen trans-represses nuclear factor kappa-B activity in human osteoblastic U2-OS cells through estrogen receptor (ER)alpha and not through ERbeta," Endocrinol. (2001) 142:1156-1166.	
	AO	Bhat, et al., "A novel estrogen receptor beta: identification and functional analysis of additional N-terminal amino acids," J. Steroid Biochem. Mol. Biol. (1998) 67:233-240.	
	AP	Pelzer, et al., "Estrogen effects in the myocardium: inhibition of NF-kappaB DNA binding by estrogen receptor-alpha and -beta," Biochem. Biophys. Res. Comm. (2001) 286:1153-1157.	
	AQ	Levin, "Cell localization, physiology, and non-genomic actions of estrogen receptors," J. Appl. Physiol. (2001) 91:1860-1867.	
	AR	Levin, "Cellular functions of the plasma membrane estrogen receptor," Trends Endocrinol. Metab. (1999) 10:374-377.	
	AS	Green, et al., "Human oestrogen receptor cDNA: sequence, expression and homology to v-erb-A," Nature (1986) 320:134-139.	
	AT	Kuiper, et al., "Cloning of a novel estrogen receptor expressed in rat prostate and ovary," Proc. Natl. Acad. Sci. USA (1996) 93:5925-5930.	
	AU	Couse, et al., "Tissue distribution and quantitative analysis of estrogen receptor-alpha (ERalpha) and estrogen receptor-beta (ERbeta) messenger ribonucleic acid in the wild-type and ERalpha-knockout mouse," Endocrinol. (1997) 138:4613-4621.	
gnd	AV	Kuiper et al., "Comparison of the ligand binding specificity and transcript tissue distribution of estrogen receptors alpha and beta," Endocrinol. (1997) 138:863-870.	

Examiner Signature	Zinna Davis	Date Considered	11/5/2004
-----------------------	-------------	--------------------	-----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

**Complete if Known**

Application Number	10/612,650
Filing Date	July 2, 2003
First Named Inventor	S. Megati
Group Art Unit	4645 / 1625
Examiner Name	Not Yet Assigned ZIONA DAVIS
Attorney Docket Number	WYTH0015-100/AM139737

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
mnd ↑	AW	Sar and Welsch, "Differential expression of estrogen receptor-beta and estrogen receptor -alpha in the rat ovary." Endocrinol. (1999) 140:963-971.	
	AX	Fitzpatrick, et al., "Expression of estrogen receptor-beta protein in rodent ovary," Endocrinol. (1999) 140:2581-2591.	
	AY	Cowley, et al., "Estrogen receptors alpha and beta form heterodimers on DNA," J. Biol. Chem. (1997) 272:19858-19862.	
	AZ	McDonnell, J., "Selective estrogen receptor modulators (SERMs): a first step in the development of perfect hormone replacement therapy regimen," Soc. Gynecolog. Invest. (2000) 7:S10-S15.	
	BA	Goldstein, "A pharmacological review of selective oestrogen receptor modulators," Human Reproduction Update (2000) 6:212-224.	
	BB	Pike, et al., "Structure of the ligand-binding domain of oestrogen receptor beta presence of a partial agonist and a full antagonist," EMBO J. (1999) 18:4608-4618.	
	BC	Shiau, et al., "The structural basis of estrogen receptor/coactivator recognition and the antagonism of this interaction by tamoxifen," Cell (1998) 95:927-937.	
↓	BD	Ogawa, et al., "The complete primary structure of human estrogen receptor beta (hER-beta) and its heterodimerization with ER alpha in vivo and in vitro," Biochem. Biophys. Res. Comm. (1998) 243:122-126.	
mnd	BE	Paige, et al., "Estrogen receptor (ER) modulators each induce distinct conformational changes in ER alpha and ER beta," Proc. Natl. Acad. Sci. USA (1999) 96:3999-4004.	

Examiner  
Signature

Ziona W Davis

Date  
Considered

11/5/2004

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.